

## **REMARKS**

### **Status of the Application**

Claims 1, 2, 4, 5, 7, 11, 12, 14, 15, 17, 19, 21 and 24-27 are all the claims that have been examined in the application. Claims 1, 3-6, 7, 11, 13-16, 17, 19 and 21-27 are rejected under 35 U.S.C. § 103(a) as obvious over JP 62-184357 in view of Knobel 5482863 and in view of Makino et al. (U.S. Patent No. 5,555,767). Claims 2 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over JP 62-184357 in view of Knobel, U.S. Patent No. 5,482,863 as applied to claims 1, 11 respectively above, and further in view of JP 64-27626 (all cited previously).

By this Amendment, Applicants are amending claims 1 and 11 and canceling claims 7 and 17.

### **Claim Rejections - 35 U.S.C. § 103**

*Claims 1, 3-6, 7, 11, 13-16, 17, 19 and 21-27 are rejected under 35 U.S.C. § 103(a) as obvious over JP 62-184357 in view of Knobel 5482863 and in view of Makino et al. (U.S. Patent No. 5,555,767).*

### **Examiner's Response to Arguments**

As seen on pages 10-15 of the instant Office Action, the Examiner was not persuaded by the arguments presented in the Amendment filed July 17, 2007. Specifically, the Examiner argues that the argument regarding unexpected results fails because the unexpected results are not commensurate with the claimed invention (the experiments were conducted using blood, while the claims are directed toward a fluid).

With regard to the argument that JP '357 fails to sufficiently stir a liquid with a high solid content, the Examiner deems the discussion of the invention with regard to the prior immaterial, as the claims in the instant application do not recite a particular solid content or solid content percent.

Finally, with regard to the argument that the method recited in claim 1 is more capable of uniform stirring high content liquid, the Examiner alleges that Applicants have failed to satisfy the burden of explaining the data evidence in support of non-obviousness, citing MPEP 716.02(b). Rather, the Examiner alleges that the measurements of the prior art of B2, C4, E5 and F3 appear to be as great as, or greater than, the measure values A1 and D5. Thus, the Examiner concludes that the evidence shown in table 2 of the declaration supports that no out of the ordinary result or benefit is provided by the instant invention.

***Submission of Declaration under 37 C.F.R. § 1.132***

Against the view of the Examiner that there is no data for plural hematocrit values for the blood specimen, Applicants have collected new data. Thus, Applicants hereby submit the experimental result of the above (refer to the following) as the attached Declaration under 37 C.F.R. § 1.132.

Applicants respectfully submit that the Examiner read the Experimental Results in the Declaration filed December 24, 2003 incorrectly.

The Applicants have argued that JP '357 is insufficient for conducting the stirring of the liquid containing much solid. However, against it, the Examiner pointed out that said argument is of no importance since the claim of the present application does not recite the particular solid

concentration. The Examiner further pointed out that Table 2 of the previously submitted Declaration (hereinafter, referred to as the previous Declaration) merely shows the usual result.

With regard to the above, the Applicants believe that the explanation to the Examiner was not sufficient in such a respect that, in the previous Declaration, the Applicants (1) conducted the experiment only for one solid concentration and (2) did not show how to interpret the data in Table 2 (such as significance of the coefficient of variance "C. V." and comparison with the reference).

Therefore, Applicants conducted the experiment once again in order to clarify the difference between the effect of the method recited in claims 1 and 11 and that of the stirring method of the citations (JP '357 and US 5,555,767). Incidentally, the experimental condition is the same as that in the previous Declaration except that (1) and (2) were taken into consideration.

The Examiner has such a view that, in the previous Declaration, the prior arts B, C, E and F in Table 2 show the numerals being as great as or greater than those in the experimental conditions A and D of the present invention, and that said Table 2 merely shows the usual result whereby that is not able to be a ground for showing the patentability.

Applicants note that it is likely that the Examiner noted that each of the data group of the experimental conditions A and D of the present invention and the Reference becomes smaller as a whole as compared with each data group of the experimental conditions B, C, E and F in the conventional inventions and that the Examiner made an erroneous interpretation that the above result should "be as great as or greater than" that of the present invention.

For example, as grounds for the above conclusion, the Examiner has a view that B2:0.6241, C4:0.6364, E5:0.6841 and F3:0.6446 in Table 2 are as great as or greater than

A1:0.6243 and D5:0.6579 of the method recited in claims 1 and 11. The data taken here, i.e., A1:0.6243 and D5:0.6579, are the smallest values among each of the data groups (A1 to A5 and D1 to D5) of each of the experimental conditions A and D.

On the other hand, B2:0.6241, C4:0.6364, E5:0.6841 and F3:0.6446 are the largest values (except the experimental condition B where it is the second largest value) among each of the data groups (B1 to B5, C1 to C5, E1 to E5 and F1 to F5) of each of the experimental conditions B, C, E and F. Thus, the Examiner appears to view that each of the experimental groups B, C, E and F is smaller than each of the data groups of the methods recited in claims 1 and 11, A and D, as a whole and that the above is interpreted that "be as great as or greater than" (that of the methods recited in claims 1 and 11).

The Examiner's interpretation of the data is incorrect for the following reasons. Firstly, with regard to the interpretation of "be as great as or greater than", it is not for the comparison of the values in each of the data groups of the experimental conditions A, B, C, D, E and F, but a distribution of each data group as a whole or, in other words, the fact whether the dispersion is big or small corresponds to the criteria for the interpretation of "be as great as or greater than". Since the total blood is completely stirred using a touch mixer in the Reference, blood cells are uniformly dispersed in the liquid. Accordingly, even when the absorbance is measured for two or more times, each data show the absorbance having almost no difference among them. Here, that which has an effect being "as great as or greater than" the Reference is a stirring method showing the similar or less dispersion to or than the Reference.

Incidentally, in the previous Declaration, "CV" is mentioned in Table 2. This is the result of making the dispersion in each data group into numerals. It shows that, when CV becomes small, dispersion of the data group also becomes small.

As will be confirmed from Table 2, the CV of the experimental conditions A and D of the present invention is able to be confirmed to be most similar to the CV of the data group of the Reference than those in other experimental conditions B, C, E and F.

Accordingly, the Applicants believe that methods recited in claims 1 and 11 have utility since it is an effective stirring method using no stirring device but using a disposing device.

***Results Based on Declaration***

In blood specimens of any hematocrit values (20, 40 and 60%), the samples A and D corresponding to the methods recited in claims 1 and 11 gave the result that it was most similar to the dispersion of the data group of the Reference than other experimental conditions as be noted from the graphs (Fig. 1-1, Fig. 2-1 and Fig. 3-1) showing the dispersion or noted from the graphs (Fig. 1-2, Fig. 2-2 and Fig. 3-2) showing the CV.

The hematocrit value shows the ratio by volume of the blood cells in the blood components. Since the above-mentioned effect was noted even in blood (hematocrit value: 60%) where concentration of blood cells or, in other words, solid component, in the blood was not less than one half, Applicants submit that the method recited in claims 1 and 11 has a much higher stirring effect in stirring of liquid containing a large amount solid when compared with JP '357.

***Arguments Regarding Claims 1 and 11***

Both cited documents and the present invention belong to the same technical field of "a field in biochemical (including immunoassay) analytical apparatuses" and concern the same problem of "a method for stirring the specimen where no stirring device is necessary."

However, with regard to the constituent feature of each of the inventions, the specimen which is an object for the stirring (an object to be uniformly suspended) is different. When the invention mentioned in each cited documents was subjected to an experiment using the specimen recited in claims 1 and 11 (i.e., blood), the resulting action and effect were found to be lower than those using the method recited in claims 1 and 11.

Therefore, although the methods recited in claims 1 and 11 are identical with the cited inventions with regard to technical field and the problem to be solved, there is a difference between them in the effect and action thereof when the citations and the methods recited in claims 1 and 11 are carried out where the constituent features are the same. Accordingly, Applicants submit that the methods recited in claims 1 and 11 are unable to be rendered obvious by a mere combination of the cited documents.

JP '357 suggests that all of specimens which are specimens for stirring are liquid (see page 32 G: Example reads "This is an automated analytical device in which a liquid reagent is added to a specimen (such as blood serum) and the reaction is investigated to conduct a test ..") On the contrary, claims 1 and 11 are directed toward a method for suspending a raw blood specimen which is not diluted with a diluting liquid. When JP '357 was applied to a blood specimen, which is a constituent feature of the specimen of the methods recited in claims 1 and 11, a lower effect than the method recited in claims 1 and 11 was noted. Therefore, Applicants

submit that use of the apparatus and method disclosed in JP '357 would result in a difficulty in achieving the results found using the methods recited in claims 1 and 11.

Knobel (US 5,482,836) uses "Magnetic particles" as a specimen and also describes a method where the magnetic particles adhered to the wall are uniformly suspended (col. 3, lines 5-46). On the contrary, in claims 1 and 11, the specimen used is "blood specimen" and there is also a description for a method where the precipitated blood particles are uniformly stirred. Knobel, fails to disclose uniform stirring of a "specimen sample" and that the existing position of the specimen before suspension is different than after suspension. Accordingly, Applicants submit that there is no motivation by which claims 1 and 11 are rendered obvious based on the disclosure of Knobel.

Makino (US 5,555,767) discloses an invention in which a blood specimen is diluted using a dilution solution (col. 1, lines 5-27 and col. 4, lines 27-41). Further, taking the fact that 200  $\mu$ l of the dilution solution is added to 10  $\mu$ l of the specimen into consideration, the diluting rate is considerably low (col. 11, lines 55-67 and col. 12, lines 18-35). On the contrary, the methods recited in claims 1 and 11 relate to suspending a raw blood specimen which is not diluted with a diluting liquid. When the invention of Makino was applied to a blood specimen, which is a constituent feature of the specimen of claims 1 and 11, the resulting effect was found to be low as compared with the methods recited in claims 1 and 11. Accordingly, Applicants submit that there is no motivation by which claims 1 and 11 are rendered obvious based on the disclosure of Makino.

Therefore, based on the above, as well as the attached Declaration under 37 C.F.R. § 1.132, Applicants submit that claims 1 and 11 are patentable over the applied art. Claims 3-5, 14, 15, 19, 21, and 24-27 are patentable at least by virtue of their respective dependencies.

*Claims 2 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over JP 62-184357 in view of Knobel, U.S. Patent No. 5,482,863 as applied to claims 1, 11 respectively above, and further in view of JP 64-27626 (all cited previously).*

Applicants treatment of JP '357 and Knobel is noted above.

JP 64/27,626 suggests that all of the specimens which are stirred are liquid (Page 171; 3. Detailed Description of the Invention "(It was) centrifuged to separate into blood and serum and only the plasma which was a supernatant liquid thereof was ... disposed, ... shaken after addition of a desired reaction solution and applied to a measuring device after the reaction whereupon the absorbance, etc. are measured.")). On the contrary, the methods recited in claims 2 and 12 relate to a method for suspending a raw blood specimen which is not diluted with a diluting liquid. Further, in JP 64-27626, there is a description for a method where the specimen is suspended by introduction of air. While, in claims 2 and 12, stirring is carried out without the use of air. Accordingly, Applicants submit that there is no motivation by which claims 2 and 12 are rendered obvious based on the disclosure of JP '626.

Therefore, claims 2 and 12 are patentable over the applied art.

### **Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the



AMENDMENT UNDER 37 C.F.R. § 1.111  
U.S. Application No.: 09/817,251

Attorney Docket No.: Q63803

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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Date: February 7, 2008